European Medicines Agency
Veterinary Medicines and Inspections

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COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE
SUMMARY OF OPINION*
ZOLVIX

International Non-proprietary Name (INN):
Monepantel

On 15 July 2009, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the veterinary medicinal product ZOLVIX, 25 mg/ml oral solution for sheep, intended as a broad spectrum anthelmintic for the treatment and control of gastro-intestinal nematode infections and associated diseases in sheep including lambs, hoggets, breeding rams and ewes. The Applicant for this veterinary medicinal product is Novartis Healthcare A/S.

The active substance of ZOLVIX is Monepantel, an anthelmintic (ATCvet Code QP52AX09) which belongs to the amino-acetonitrile derivative class of molecules and acts on the nematode specific nicotinic acetylcholine receptor sub-unit Hco-MPTL-1.

The benefits of ZOLVIX are its broad spectrum anthelmintic properties and effectiveness against strains of parasites resistant to (pro)benzimidazoles, levamisole, morantel and macrocyclic lactones.

The approved indication is: as a "broad spectrum anthelmintic for the treatment and control of gastro-intestinal nematode infections and associated diseases in sheep including lambs, hoggets, breeding rams and ewes".

Detailed conditions for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for ZOLVIX and therefore recommends the granting of the marketing authorisation.

* Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the Opinion.

** Applicants may appeal any CVMP opinion, provided they notify the EMEA in writing of their intention to appeal within 15 days of receipt of the opinion.

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